

§ 520.2611

21 CFR Ch. I (4–1–05 Edition)

adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

(2) The drug is given orally at 30 milligrams per kilogram of body weight per day (14 milligrams per pound per day), or as follows:

Animal body weight (pounds)	Number of tablets
30 MG TABLETS	
2.2	1
4.4	2
6.6	3
8.8	4
120 MG TABLETS	
Up to 9	1
10 to 19	2
20 to 29	3
30 to 40	4
480 MG TABLETS	
30 to 40	1
40 to 60	1½
60 to 80	2
80 to 110	3
Over 110	4

(3) The drug is given once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis.

(4) Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

(7) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 3853, Jan. 27, 1976, as amended at 44 FR 32214, June 5, 1979; 46 FR 23231, Apr. 24, 1981; 47 FR 36814, Aug. 24, 1982; 50 FR 9800, Mar. 12, 1985; 50 FR 11852, Mar. 26, 1985; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2611 Trimethoprim and sulfadiazine oral paste.

(a) *Specifications.* Each gram of oral paste contains 400 milligrams (67 milligrams of trimethoprim and 333 milligrams of sulfadiazine).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter for product to be dosed at 5 grams per 150 pounds of body weight per day. See No. 000061 in § 510.600(c) of this chapter for product to be dosed at 3.75 grams per 110 pounds of body weight per day.

(c) *Conditions of use*—(1) *Dosage.* (i) 5 grams (335 milligrams of trimethoprim and 1,665 milligrams of sulfadiazine) per 150 pounds (68 kilograms) of body weight per day. (ii) 3.75 grams (250 milligrams of trimethoprim and 1,250 milligrams of sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For horses where systemic anti-bacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) *Limitations.* Administer orally, once a day, as a single dose for 5 to 7 days; daily dose may also be halved and given morning and evening; for acute infection therapy continue treatment 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for prolonged use; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 34469, July 29, 1983, as amended at 49 FR 26714, June 29, 1984; 53 FR 11063, Apr. 5, 1988; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]